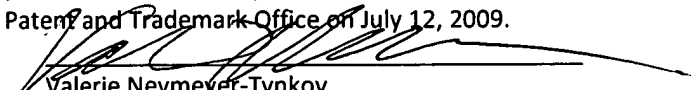


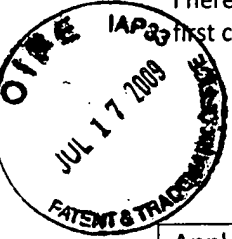
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Certification under 37 CFR 1.8

I hereby certify that this paper (along with any paper referred to as being associated herewith) is being mailed by first class mail or by USPO Express Mail to the US Patent and Trademark Office on July 12, 2009.


Valerie Neymeyer-Tynkov



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.:	09/890,371
Applicant:	Cevc, et al.
Examiner:	Bruce D. Hissong
Art Unit:	1646
Title:	TRANSNASAL TRANSPORT/IMMUNISATION WITH HIGHLY ADAPTABLE CARRIERS
Customer No.:	85965

Mail Stop Amendment

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (IDS)

This letter and the attached forms 1449/PTO are submitted after the issuance of a first Action but before the issuance of a final Action or Notice of Allowance in the present application. The Commissioner is authorized to charge Deposit Account No. 50-4939 in the amount of \$180 (according to Rule 1.17(p)) to pay for the submission of this IDS; while no other fees are believed to be due at this time, the Commissioner is also authorized to charge any further fees that may be deemed as due in this application, or to credit any overpayment.

A copy of Documents UA-US, UU-UW is not submitted with this IDS, in keeping with USPTO policy regarding the submission of published US documents. However, a copy of the bibliographic page of each of these documents is included for the Examiner's convenience.

Documents UA-UB, UD-UJ, US and UV-UW are US applications or granted US patents that may relate to penetrant technology or other elements of the present invention. Documents VA-WB include substantive Office Actions, Notices of Allowance and described claim sets issued in these and/or other applications (including applications previously disclosed to the USPTO in the present application in the IDS filed August 2007 with relevant claim sets). Entries in the attached IDS include application status and the surname of the Examiner currently in charge of examination of the application.

* Possible state-of-the-art document not disclosed in a previous IDS.

In particular, please note that claims of pending Application No. 09/890,335 are patentably distinct from those of the present invention but include some claim limitations similar to limitations of the present claims. Other applications and their Actions disclosed herein relate to US national stage applications based on PCT applications incorporated by reference at page 13 of the application as filed, and/or to applications disclosed as relevant to the present invention in the IDS filed in August 2007 in this application (submitting copies of claims in Document/Cite Nos. CU-CB1).

Applicant respectfully notes that this submission is provided to ensure compliance with and full respect for the duty to disclose material information to the USPTO and the duty of good faith and candor with the USPTO. However, as the number of pages submitted with the present IDS is nearly 1000 pages, to avoid overburdening the Examiner, a copy of the version of claims pending in a given application at the time of the most recent Office Action or a copy of claims that have been granted by the USPTO is submitted with regard to each application with this IDS. Other claim sets in these applications should be readily available through Public PAIR or other databases at the USPTO. Documents such as Interview Summaries, Responses to Office Actions and Inventor Declarations are also not included with this IDS, in the interests of minimizing the number of documents submitted with this IDS, as the submission of arguments for patentability is not required under the duty to disclose, and as Interview Summaries are not likely to provide a better prima facie case against patentability than an Office Action. In view of the more similar claim language of the present claims and those of US 09/890,335, a copy of Interview Summaries issued by the Examiner and a recent set of claims filed in that application are also included with the present IDS. Applicant will be pleased to submit any other file history documents related to any of these applications upon request; at present, it is uncertain whether the Examiner will find any of these documents useful or material while continuing examination in the present application. Double-patenting rejections occur with regard to some of these applications/patents, but not with relation to the present application, and so these rejections have not been detailed below. The disclosure of this information is made in good faith and is believed to be representative of prosecution in these applications and compliant with the duties owed to and imposed by the USPTO. See below for a brief discussion of representative Office Actions included with the present IDS including rejections based on alleged prior art documents.

Documents WC-WE were issued during the international stage of the PCT application on which the present application is based. During international examination, documents D1-D3 (EP 0 475 160, WO 98/17255 and DE 41 07 152) were cited against the novelty of the claimed invention. Documents D4 and D5 (Almeida et al., J. Drug Targeting 3(6):455-67 (1996), and WO 90/093885) were cited against the inventiveness of the invention. Each of these documents was previously disclosed in the present application.

The international stage took place before the European Patent Office (EPO). Documents WF-WH relate to prosecution and grant of the counterpart EPO application. A copy of the English version of claims granted by the EPO is also attached. It is recognized that the EPO operates under different rules and different laws than the USPTO, however, as documents relating to EPO prosecution are relatively short, the documents are submitted for the Examiner's convenience. EP 0 475 160 and the Almeida document mentioned above were discussed with regard to the novelty and inventiveness of the European claims during prosecution.

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With regard to the IDS filed in this application in October 2003, please note that DE 41 07 152 and DE 44 47 287 were incorporated into PCT Appln. Nos. PCT/EP1991/001596 (published as WO 1992/03122 and equivalent to US 6,165,500) and PCT/EP1996/004526 (published as WO 1998/17255 and equivalent to US 2002/048596), respectively. Also, in the present IDS, Document UT (DE 40 26 834.9) is incorporated into PCT/EP1991/001596 (published as WO 1992/03122 and equivalent to US 6,165,500). Each of these PCT applications and/or its equivalent is indicated as considered by the Examiner in the file history of this application.

The Office Action issued on January 26, 2009 in US Appln. No. 09/890,335 (currently pending) includes rejections under 35 USC 102(b) over Paul et al (Vaccine Res. 4:145-164 (1995)), and under 103(a) in view of WO 98/20734 and Paul et al. The Office Actions issued on May 1, 2008, July 18, 2007 and May 25, 2006 in the '335 application include rejections under 102 and/or 103 as indicated above, and rejections under 35 USC 112.

The Office Action issued on January 3, 2006 in US Appln. No. 09/621,574 (abandoned) includes rejections under 35 USC 112, 35 USC 102(b) over EP 0 220 797, and under 103(a) in view of EP 0 220 797 and Lau (5,104,661), and in view of EP 0 220 797 and Quinn (4,666,747). A Supplemental Notice of Allowability was mailed March 2, 2005. A Notice of Allowability and Action mailed July 2, 2001 includes rejections under 35 USC 112, under 102(b) over EP 0 220 797 and in view of Mayer (BBA, 1986), and under 103 in view of EP 0 220 797, Mayer, Patel (FEBS Letters) and Wallach (4,911,928).

Office Actions issued on May 25, 1999, June 24, 1998, and December 19, 1997 in US Appln. No. 07/844,664 (now US Pat. No. 6,165,500) include rejections under 35 USC 112, under 102(b) over EP 0 220 797 and in view of Mayer (BBA, 1986), and under 103 in view of EP 0 220 797, Mayer, Patel (FEBS Letters) and Wallach (4,911,928) (latter two Actions only).

The Office Action issued on March 27, 2007 in US App. 11/481,804 (Published as US 2007/0042030) includes rejections under 35 USC 112, and under 35 USC 102 and/or 103 in view of EP 0 220 797, US 4,731,210 (Weder), US 5,104,661 (Lau) and US 4,666,747 (Quinn).

The Office Actions issued in US App. 09/555,986 on Aug 10, 2006 and Dec 21, 2005 include rejections under 35 USC 112, under 35 USC 102 over US 4,731,210 (Weder), and 35 USC 103 in view of Weder alone or in combination with WO 92/03122. The remaining Actions include rejections under 35 USC 112, rejections under 102 in over WO 92/03122 or Weder or Uster (4,944,948) or Klibanov (BBA, 1991) or CA 2 052 164, and/or under 103 in view of 92/03122 alone or combined with Uster or Weder or Klibanov. The May 20, 2003 Action further included a rejection under 35 USC 101 to "use"-style claims.

The Office Actions issued in US App. 09/284,683 on November 25, 2008 and April 2, 2008 include rejections under 35 USC 112 and under 35 USC 103 in view of Vyas (J. Microencapsulation, 1995) or Hayward (5,585,109) or Sheffield (4,937,254) in combination with Radhakrishnan (5,043,165)*, Edgar (5,498,420) * by themselves or further in combination with Mezei (4,897,269)*. The Action issued November 29, 2007 includes rejections under 35 USC 112 and under 35 USC 103 in view of Vyas or Hayward or Sheffield in combination with Mezei, and further mentions US 2007/0243203* (page 4 of Action, bottom). The August 17, 2007 Action includes rejections under 35 USC 112, under 35 USC 102 over Sheffield or Hayward, and under 103 in view of Hayward or Sheffield in combination with Unger

* Possible state-of-the-art document not disclosed in a previous IDS.

(5,209,720). The March 12, 2007 Action includes rejections under 35 USC 112, under 35 USC 102 and 103 in view of Lichtenberger (5,763,422) or Ghyczy (4,369,182), and under 103 in view of various combinations of Hayward, Lichtenberger, Ghyczy, and/or Unger. The July 10, 2006 and November 4, 2005 Actions include rejections under 35 USC 112, under 102 over Blume et al (J. Liposome Research 1992) or EP 0 475 160 (equivalent to US 6,165,500, discussed above), and under 103 in view of Blume and EP 0 475 160 or EP 0 475 160 alone. The Action dated April 15, 2005 includes rejections under 35 USC 102 and 103 in view of EP 0 475 160. The Actions dated June 24, 2004, October 7, 2003, January 3, 2003, and April 10, 2002 include rejections under 35 USC 112 and under 35 USC 102 and 103 in view of EP 0 475 160. The Actions dated April 20, 2001 and August 22, 2000 include rejections under 35 USC 112, under 102 and 103 in view of EP 0 220 797, Roberts (4,921,706), Mayer (BBA, 1986), Blume, EP 0 707 847 (Bayer), or EP 0 704 206 (Regenold).

The Office Actions issued December 30 and November 28, 2008 in US App. 11/667,325 include rejections under 35 USC 112 and under 103 in view of Cevc 2004/0071767 and Rovee (US 4,185,100)*. The Examiner also indicates "Itching" (2006)* as a document of interest.

The Office Actions issued on May 26, 2009 and October 28, 2008 in US App. 10/357,618 include rejections under 35 USC 112 and under 35 USC 103 in view of DE 40268349* (Cevc) alone or with US 4,938,970*; and in view of US 6,165,500 and US 4,938,970*. The Office Action issued March 19, 2008 includes rejections under 35 USC 112, 35 USC 102 over US 6,165,500, and 35 USC 103 in view of EP 0 220 797 and US 6,165,500. The Office Action issued August 2, 2007 includes rejections under 35 USC 103 in view of EP 0 220 797 and Carafa et al. ("Lidocaine-loaded non-ionic surfactant vesicles: characterization and in vitro permeation studies" International Journal of Pharmaceuticals 231:21-32 (2002), and also mentions Carafa in a provisional double patenting rejection. The Office Action issued December 28, 2006 includes rejections under 35 USC 112 and under 35 USC 102 over WO 00/38653.

The Notices of Allowability issued October 16, 2008 in US App. 10/357,617 include reasons for allowance of claimed subject matter. The Office Action issued September 21, 2007 includes rejections under 35 USC 112 and under 35 USC 103 in view of Cevc (Critical Reviews in Therapeutic Drug Carrier Systems, 12:257-388 (1996)) and WO 00/38653; and in view of EP 0 220 797 alone or with WO 00/38653. The Actions issued January 19, 2007 and May 30, 2006 include rejections under 35 USC 112, under 35 USC 102 over EP 0 220 797, Needham (6,200,598), Needham (6,726,925*), Cevc (Critical Reviews, 1996), WO 98/17255, or Cevc (Biochim. Biophys. Acta 1514:191-205 (2001); and under 35 USC 103 in view of various combinations of EP 0 220 797 (alone or in combination), Needham (6,726,925)*, and in view of WO 00/38653, Cevc (Critical Reviews, 1996), Needham (6,200,598) and/or EP 0 220 797. The May 30, 2006 Action (page 4, bottom) also mentions EP 1 031 346 pages 16-18.

The Office Actions issued on May 16, 2007, August 28, 2006 and February 7, 2006 in US App. 10/984,450 include rejections under 35 USC 112, under 35 USC 102 over US 6,165,500, and under 35 USC 103 in view of US 6,165,500.

The Office Actions issued January 9, 2008 and April 11, 2007 in US App. No. 10/037,480 include rejections under 35 USC 112 and under 35 USC 103 in view of WO 90/09385 or WO 00/44349, and indicate allowable subject matter (no 103 rejection in the April '07 Action). The Action issued September 20, 2006 includes rejections under 35 USC 102 over US 6,165,500, and indicates allowable

* Possible state-of-the-art document not disclosed in a previous IDS.

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subject matter. The Action issued December 19, 2005 includes rejections under 35 USC 112 and under 35 USC 102 over US 6,165,500. The Action issued March 30, 2005 includes rejections under 35 USC 112, 35 USC 102 over WO 98/17255, and 35 USC 103 in view of WO 98/17255 and Unger (US 6,028,066). The Action issued October 16, 2003 includes rejections under 35 USC 112 and under 35 USC 103 in view of RE.33,273 (Speaker), and indicates allowable subject matter. The Notices of Allowability issued August 21, 2008 and July 21, 2004 in US App. No. 10/037,480 include reasons for allowing claimed subject matter.


The Office Action issued Oct 19, 2005 in US App. 09/887,493 includes an objection to one claim as improper, and indicates other pending claims as allowed. The Office Action of Feb 2, 2005 includes rejections under 35 USC 112 and under 35 USC 103 in view of DE 44 47 287 C1 and US 5,322,685 and Cevc (J. Controlled Release 45:211-226 (1997)). The Advisory Action of May 27, 2004 maintains certain rejections raised in the Action of Nov 4, 2003, which includes rejections under 35 USC 102 in view of DE 44 47 287 C1 and US 5,322,685. The Action issued June 17, 2003 includes rejections under 35 USC 102 over DE 44 47 287 C1 and under 103 in view of DE 44 47 287 C1 and US 5,322,685,. The Action issued November 29, 2002, includes rejections under 35 USC 112, 35 USC 102 over DE 44 47 287 C1, and under 35 USC 103 in view of DE 44 47 287 C1 and US 5,322,685.

The Office Action issued October, 23 2008 in US App. 11/638,091 includes rejections under 35 USC 112, 35 USC 102 over Cevc (J. Controlled Release 45:211-226 (1997)), and 35 USC 103 in view of DE 44 47 287.

Information disclosed herein is believed to be complete and within the meaning of the duty to disclose information and the duty of good faith and candor imposed by the USPTO. No information that should be submitted in compliance with these duties has been intentionally omitted from this letter or from the accompanying Information Disclosure Statements and documents attached thereto. In the event that any material, non-cumulative information is deemed missing, it is noted that such omission was made in error, and without any intent to withhold information from the USPTO.

Information submitted in this IDS is not meant to indicate that a search has been made, or that any given document is prior art in the context of the present invention. Page/line numbers of relevant passages mentioned by examining bodies are described for instance in the attached Office Actions and Search Reports.

Respectfully submitted,



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* Possible state-of-the-art document not disclosed in a previous IDS.